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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,446	02/09/2004	George Inana	39532-192229	4156

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,446	INANA ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39 and 53-62* is/are pending in the application.

4a) Of the above claim(s) *14 and 18-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-17 and 53-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments filed 8/11/05 and 8/19/05, are acknowledged.

Claims 40-52 have been cancelled.
Claims 53-62 have been added.
Claims 1-2, 4, 7-8, and 13 have been amended.
Claims 1-39 and 53-62 are pending.

2. Applicant's election with traverse of group V, drawn to a method of delaying or reversing a retinal or choroidal degenerative disease using an agent that modulates expression or activity of SEQ ID NO;15, claims 2-13, 15-17 and 53-62 in the reply filed on 12/9/04 is acknowledged. Furthermore, applicant has elected an RPE cell as the species to be examined first.

Applicant's traversal is on the grounds that the restriction/election requirement does not comply with the U.S.P.T.O Guidelines as set forth in MPEP 803.04 which states that it "has been determined that normally ten sequences constitute a reasonable number for examination purposes". Applicant further requests that the examination of the sequences of SEQ ID NOS 1-9 be examined along with SEQ ID NO: 15. This is not found persuasive because the MPEP is merely a guideline, and as the technology has progressed, examination of up to ten independent and distinct sequences in a single application without restriction has proven to be unduly burdensome on the Office. As a result, examination generally is limited to a single sequence. The different sequences are distinct and independent, and searches of all the sequences would place an undue burden upon the examiner due to the distinct and divergent subject matter of each Group. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made final.

Therefore, the remaining SEQ ID NOS and Claims 14 and 18-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 2-13, 15-17, 53-62, and linking claim 1 read on the elected invention and are being acted upon.

3. Applicant's information disclosure, filed 4/1/05, is acknowledged. Applicant is required to provide the date for Reference S.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 53-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "modulates" in claim 1 is indefinite because it is not clear what direction of modulation is required (i.e. increasing or decreasing the expression or activity of AMDP genes). The term modulate could be interpreted in a variety of ways. For example modulate could indicate that AMDP genes are turned on or off, or could also indicate that they are upregulated or downregulated to an unspecified degree. In addition, said modulation could be intermittent, or constant. Since the instant specification does not define the meaning of modulate, it not clear what degree, direction, or type of modulation is required for the claimed invention to function as a method of delaying a disease. As claims 2-12 and 53-62 depend from claim 1, and do not clarify the indefiniteness of the invention, they are also rejected.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15-17, and 53-62 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A method comprising contacting an extracellular matrix of a retina or choroid" (Claim 1, and dependant claims 2-13, 15-17 and 53-62).

B) A method for delaying a disease comprising contacting a cell with an agent that modulates the expression of a gene "or product thereof" (Claim 1 and 2 and dependant claims 3-13, 15-17 and 53-62).

C) The method where the extracellular matrix is in the retina, choroid, or vitreous (Claims 54-56).

D) The method wherein the antibody is administered by intraocular injection, to the retina, subretinal space, choroid, or vitreous (Claims 58-62).

In the Preliminary Amendments, filed 8/11/05 and 8/19/05, Applicant indicates that support for the new limitations of Claim 1 can be found at pages 8 and 31 of the specification.

A review of the specification fails to reveal support for the new limitations.

Regarding A), at page 8, the specification discloses, "the AMDP-related or phagocytosis related gene...may be located within the cell or in an extracellular matrix." Note that the specification does not disclose contacting an extracellular matrix with an agent, merely that the AMDP related gene to be modulated may be in the extracellular matrix.

Regarding B), at page 31, the specification discloses, "Preferred genes/proteins to be targeted..", however, it does not specifically state modulating genes or products thereof. While a protein may be inferred to be a product of a gene, this specific example is insufficient to support the claims that recite the broad statement of a gene "or product thereof."

Regarding C), the specification as filed does not provide a written description for the limitation of claims 54-56, where the extracellular matrix is in the retina, choroid, or vitreous.

Regarding D), at pg. 53, the specification discloses delivery of a vector by intraocular injection. However, the disclosure does not recite administering an antibody. It is

noted that all cites relating to administration of an antibody are found in specific examples and not in generic disclosures. Thus, Applicant has improperly attempted to claim specific limitations set forth only in specific examples of the more generic claims of the instant application.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13, 15-17, 53-62 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US Patent application publication 2003/0199440 as evidence by US Patent application publication 2005/0059595.

The '440 patent application teaches a method for the treatment of damaged tissues associated with age-related macular degeneration (AMD) by administering an inhibitor of adverse proteases (see paragraphs 216-218, and claim 11). Treatment is defined, in one embodiment, as being curative (see paragraph 75), and hence this method will reverse and delay AMD. The specification of the '440 patent application further discloses that said inhibitor can be specific for MMP14 (see paragraph 222), which shares 99.9% sequence identity with the MT1-MMP of the instant application. Furthermore, said inhibitor can be an antibody (paragraph 309). Claim 6 is included since the '440 patent application teaches that "treatment" includes prophylactic treatment (see paragraph 75). Claim 13 and 16 are included since the '440 patent application teaches that the treatment inhibits the specific proteolytic degradation effects of MMP14 (paragraph 68), i.e. downregulates/ neutralizes its

activity. Furthermore, claims 17 is included since '440 further teaches that matrix metalloproteinases are endopeptidases that degrade the extracellular matrix. Therefore, inhibition of the proteolytic degradation effects of MMP14 would inherently lead to loss of extracellular matrix degradation activity. Claim 57 is included since '440 teaches that an antibody can be monoclonal (paragraph 499). Claim 58 is included since '440 teaches that the inhibitor (i.e. antibody) can be given by intraocular administration (see paragraph 63). Claims 9, 12 and 54-62 are included since US Patent application publication '595 teaches that intraocular injection can allow diffusion throughout the vitreous, the entire retina, and the choroid. Thus, administration via an intraocular route would also have inherently administered the antibody to the retina (including the subretinal space, an RPE cell, and the interphotoreceptor matrix or intracellular matrix of said retina), the choroid (including the extracellular matrix of the choroid), and the vitreous (including the extracellular matrix of the vitreous). Claims 10-11 are included since the location of MT1-MMP is inherent to AMD (see pg. 62 of the instant specification) Therefore, since the '440 application involves treating AMD, the MT1-MMP (MMP14) would have inherently been located in the RPE cell and extracellular matrix.

Thus the reference clearly anticipates the invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
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September 2, 2005

9/3/05
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER